

Appl. No.: 09/923,626
Group Art Unit: 1616
Response to Paper No. 10

REMARKS

Claims 1-19 are currently pending in the present application.

At the outset, Applicants would like to note that while the Examiner has acknowledged the absence of the Form PTO-892 referenced in Paper No. 8 (*see*, Paper No. 10, p. 3), no copy of the Form PTO-892 was attached to Paper No. 10 and no copy has been received by Applicants' undersigned representative. Applicants respectfully request that the Examiner forward a copy of the Form PTO-892 with her next communication to Applicants, along with copies of the references cited.

The Examiner's Rejection of Claims 1-19 Under 35 U.S.C §103(a):

In Paper No. 10, the Examiner maintains the rejection of claims 1- 19 under 35 U.S.C. §103(a), as being unpatentable over "Fizet (abstract of EP 610742, U.S. Patent 5,487,817)," and makes the rejection final. (*See*, Paper No. 10, pp. 3-4). Applicants again note that all references to "Fizet" made herein apply to the U.S. Patent, *e.g.*, column and line numbers thereof.

In maintaining the rejection, the Examiner again contends that Fizet discloses a process for recovering tocopherols and sterols from natural sources, and she argues that this disclosure somehow "embraces Applicant's [*sic*] claimed invention." (*See*, Paper No. 10, p. 3). The Examiner continues to contend that Fizet discloses a process "for isolation of sterols" which includes (a) esterifying sterols with fatty acids, (b) distilling the resulting mixture to produce a residue of sterol esters, (c) cleaving the sterol esters to form free sterols and (d) isolating the sterols from the residue. The Examiner then contends that the instant claims differ from the prior art only in that they cite conditions for the reactions and classify the cleavage of the ester as transesterification. The Examiner then summarily argues that "[i]t would have been obvious to one skilled in the art at the time of invention to isolate sterols from the mixture by first transesterif[ying] the mixture to get the sterols esters and then separating other products by distillation or any other means and then cleaving the sterol to break the ester bond with sterol to get free sterol." (*See, id.* at p.3).

Appl. No.: 09/923,626
Group Art Unit: 1616
Response to Paper No. 10

On this basis, the Examiner concludes that the subject matter of the instant claims would have been obvious within the meaning of 35 U.S.C. §103(a).

Applicants' Traversal of the Rejection Under 35 U.S.C. §103(a):

Applicants strenuously traverse the Examiner's rejection, along with her contentions and arguments in support thereof for the following reasons.

Fizet fails to disclose a process for isolating sterols from an oil distillation residue containing sterol esters and partial glycerides, wherein two separate transesterifications, under different conditions are carried out, as claimed. In contrast, what Fizet discloses is a process for recovering tocopherols, and optionally, sterols from deodorizer sludges. Ultimately, the oil distillation residue produced via the process disclosed in Fizet, and which contains "the majority of sterol esters which are formed in the [initial direct] esterification" is subjected to a single transesterification, whereby the yield of sterols is optimized via catalysts, solvents and harsh reaction conditions. (See, Fizet, col. 5, lines 46-67). Applicants' claimed invention is an economic and ecological improvement over such prior art processes in that such solvents are avoided and higher purity is more easily attained. (See, Applicants' Spec., p. 1, lines 4-21).

Fizet discloses a process which begins with a deodorizer sludge containing tocopherols, sterols, fatty acids and other components. The sterols present in the sludge are first esterified with fatty acids present in the sludge, i.e., a direct esterification. This esterified sludge containing sterol fatty acid esters, fatty acids, tocopherols and various other components is then distilled twice to remove a first fraction containing fatty acids, and a second fraction containing tocopherols. (See, e.g., Fizet, claim 1, subsection (b)). The eventual residue obtained after the distillations and other processes designed to remove the tocopherols, i.e., the oil distillation residue, contains sterol fatty acid esters along with triglycerides, other waxes, and numerous other high-molecular weight substances. (See, Fizet, col. 5, lines 46-53). Fizet discloses that sterols may be obtained from the residue via acid-catalyzed transesterification carried out in a steel autoclave over a period of from 1 to 5 hours. (See, *id.* at lines 53-64). This harsh, single

Appl. No.: 09/923,626
Group Art Unit: 1616
Response to Paper No. 10

transesterification step wherein glycerides, tocopherol esters, sterol esters and numerous other substances are all simultaneously transesterified is avoided by Applicants' claimed invention.

Applicants' claimed invention provides a process which begins with an oil distillation residue containing sterol esters and partial glycerides. The oil distillation residue is then subjected to a first mild transesterification to split the glycerides into fatty acids and glycerol. These components can then be removed, for example, via distillation. The remaining sterol esters can then be transesterified apart from the original complex mixture of glycerides, waxes and other components present in the oil distillation residue.

More specifically, Applicants' claimed invention is directed to a surprisingly economical and environmentally friendly process for producing sterols, wherein the process comprises two separate transesterification steps. (See, Applicants' Specification, page 2, lines 25-27). Applicants' claimed process comprises: (a) providing an oil distillation residue comprising sterol esters and partial glycerides; (b) transesterifying the partial glycerides with a lower alcohol in the presence of a basic catalyst under mild transesterification conditions to form fatty acid alkyl esters and glycerol; (c) removing excess lower alcohol, the basic catalyst, the glycerol and the fatty acid alkyl esters, to form a bottom product comprising the sterol esters; and (d) transesterifying the sterol esters at a temperature of from 90°C to 145°C and a pressure of from 2 to 10 bar for a period of from 4 to 10 hours to form free sterols.

Applicants respectfully submit that the teachings of Fizet are insufficient to establish a *prima facie* case of obviousness with respect to the claimed invention.

As the Examiner is well aware of, prior to rendering an ultimate conclusion of obviousness during the examination of a U.S. utility patent application, the Examiner must first establish a *prima facie* case of obviousness, which Applicants may then rebut with argument and evidence, which may then be evaluated in making a final determination of obviousness.

(M.P.E.P. §2142).

It is well-settled that in order to establish a *prima facie* case of obviousness based upon a single reference, and thus shift the burden of proving non-obviousness onto Applicants, the Examiner MUST satisfy each of the following three criteria: (1) the reference must contain a

Appl. No.: 09/923,626
Group Art Unit: 1616
Response to Paper No. 10

teaching or suggestion which would motivate one of ordinary skill in the art to modify the reference as suggested by the Examiner (it is not sufficient to say that the reference can be modified without a teaching in the cited reference to suggest the desirability of such a modification); (2) there must be a reasonable expectation of success; and (3) the reference must teach or suggest each and every element of Applicant's claimed invention. The teaching or suggestion to modify the cited art and the reasonable expectation of success must both be found in the prior art and not in Applicants' Specification (M.P.E.P. §2143).

Fizet clearly fails to teach or suggest each and every element of Applicants' claimed invention. First, Fizet does not teach or suggest the transesterification of an oil distillation residue containing sterol esters and partial glycerides under mild conditions whereby the sterol esters remain substantially bound as esters. Such a transesterification is not even suggested. Fizet clearly teaches the treatment of the sterol ester-containing residue via a single transesterification to obtain free sterols. Furthermore, the reference fails to suggest a two-step transesterification with an intervening separation of glycerol and other unwanted compounds from the sterol esters. Fizet specifically provides for sterol yield optimization through the solvent/catalyst/reaction condition options avoided by Applicants' claimed process. (See, Fizet, col. 5, lines 64-67).

Moreover, Fizet contains no teaching or suggestion which would motivate one of ordinary skill in the art to modify Fizet as suggested by the Examiner in order to arrive at Applicants' claimed invention. Fizet does not teach or suggest subsequent treatment of the sterol ester-containing residue other than the single harsh transesterification. The residue is simply transesterified under normally harsh conditions whereby all substances are simultaneously transesterified, and subsequent purification, *e.g.*, via crystallization, is performed. Nothing in Fizet suggests the claimed two-step transesterification. Nor is there any suggestion that the sterol esters should be concentrated prior to final transesterification via Applicants' claimed mild transesterification and separation of glycerol, etc. Fizet clearly recognizes the presence of many other compounds in the sterol ester-containing residue.

Appl. No.: 09/923,626
Group Art Unit: 1616
Response to Paper No. 10

Given the lack of any teaching or suggestion to modify the reference as suggested by the Examiner, and that fact that the reference otherwise fails to teach or suggest each and every element of the claimed invention, one of ordinary skill in the art would find no reasonable expectation of successfully achieving the claimed invention in the teachings of Fizez.

Accordingly, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness, as none of the three criteria necessary to establish a *prima facie* case of obviousness has been satisfied. Thus, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

In view of the remarks set forth above, Applicants submit that all pending claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejection and a Notice of Allowance for all pending claims are respectfully requested.

Respectfully submitted,

MEHDI BONAKDAR, *et al.*

August 9, 2003
(Date)

By: 

AARON R. ETTELMAN
Registration No. 42,516
COGNIS CORPORATION
2500 Renaissance Blvd., Suite 200
Gulph Mills, PA 19046
Telephone: (610) 278-4930
Facsimile: (215) 278-4971
E-Mail: aaron.ettelman@cognis-us.com

ARE:are

OFFICIAL